

Elizabeth Kavaler, M.D.

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IN THE CIRCUIT COURT  
TWENTY-SIXTH JUDICIAL CIRCUIT  
CAMDEN COUNTY, MISSOURI

- - -

DONALD BUDKE	:
Plaintiff,	:
v.	:
JOHNSON & JOHNSON, a NEW	:
Jersey Corporation, ETHICON	:
INC., a New Jersey Corporation,	:
GYNECARE WORLDWIDE, a division	:
of Ethicon, Inc., BECKY	:
SIMPSON, M.D., P.C., d/b/a	: Cause No.
LAKE AREA WOMEN'S CENTER	: 10CM-CC00085
and BECKY SIMPSON, M.D.,	:
Defendants.	:

- - -

OCTOBER 14, 2014

- - -

Videotaped deposition of  
ELIZABETH KAVALER, M.D., taken pursuant  
to notice, was held at the law offices of  
Bryan Cave LLP, 1290 Avenue of the  
Americas, New York, New York 10104,  
commencing at 10:37 a.m., on the above  
date, before Amanda Dee Maslynsky-Miller,  
a Certified Realtime Reporter and Notary  
Public in and for the State of New York.

- - -

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1                   product and how to compare it to  
2                   the way I was -- I was shown how  
3                   to use it.

4                   But a lot of the information  
5                   in there is not something that I'm  
6                   looking to Ethicon to tell me.

7   BY MR. SLATER:

8                   **Q.**    I understand you're smart  
9                   and you don't need it, but other doctors  
10                  may not --

11                  MR. BALL: I move to strike  
12                  the --

13   BY MR. SLATER:

14                  **Q.**    Let me ask you this --

15                  MR. BALL: -- the  
16                  argumentative preamble.

17   BY MR. SLATER:

18                  **Q.**    -- do you think Ethicon has  
19                  an obligation, and had an obligation,  
20                  with the PROLIFT® IFU that when they put  
21                  information in it, that Ethicon thought  
22                  the information was truthful?

23                  MR. BALL: Object to the  
24                  form.

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1                   THE WITNESS: I don't put  
2                   this much thought into the IFU. I  
3                   don't know any surgeons who do put  
4                   that much into the IFU.

5 BY MR. SLATER:

6                   **Q.**        You don't have an opinion on  
7                   that?

8                   **A.**        I don't really have much of  
9                   an opinion on the IFU.

10                  **Q.**        Okay. If I understand  
11                  correctly, you, in your practice, didn't  
12                  even the read the section of the warnings  
13                  and indications and adverse reactions;  
14                  that wasn't even something that you  
15                  looked at, correct?

16                  MR. BALL: Object to the  
17                  form.

18                  THE WITNESS: I read it. I  
19                  looked at it. But that wasn't the  
20                  basis for which I would use it or  
21                  not use it.

22 BY MR. SLATER:

23                  **Q.**        Did I ask you if that was  
24                  the basis for which you would use it or

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1 MR. SLATER: So we have a  
2 disagreement.

3 MR. BALL: -- you're right.

4 MR. SLATER: It doesn't  
5 matter. That's why we have a  
6 judge.

7 BY MR. SLATER:

8                   **Q.**        You never used the patient  
9 brochure in your practice, right?

10                   **A.**           That's right.

11                   **Q.**     As you sit here now, you  
12   have no opinions about whether or not the  
13   information in the patient brochure was  
14   adequate or not, correct?

15 MR. BALL: Object to the  
16 form.

17 THE WITNESS: I've read it.

18 I think it's adequate. I don't  
19 know what the obligations are, but  
20 it's adequate.

21 So I have read it. I didn't  
22 use it. And I think it's adequate  
23 information.

24 BY MR. SLATER:

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1                   **Q.**     And what's the standard by  
2 which you're judging whether or not the  
3 information in the patient brochure is  
4 accurate? Define for me that standard.

5                   **A.**     Well, "adequate" is a  
6 judgment, right? It's a subjective  
7 assessment of what's right or wrong.

8                   **Q.**     So it's your personal  
9 opinion?

10                  **A.**     Right. So adequate, to me,  
11 is that it covers the bases, it gives you  
12 a general idea of what's involved. But  
13 it's really a tool for a conversation  
14 between the patient and the doctor.

15                  **Q.**     Something you never used it  
16 for, right?

17                  **A.**     I never used it for that  
18 because I did my own.

19                  **Q.**     Let me ask you this -- to go  
20 back to some of the questions I asked you  
21 on the IFU, I'm going to ask a few of  
22 them for the patient brochure.

23                   When Ethicon provided  
24 information in the patient brochure for

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1                   **A.**     Can you be more specific in  
2 what you want me to answer?

3 Q. Sure.

With regard to the various prolapse meshes you've used over the years, do you know the difference in pore sizes between the different devices?

11                   **A.**       Not specifically. But I  
12                   know they are all within the same --  
13                   they're all Type 1 meshes, all their pore  
14                   sizes are of a certain size that's  
15                   acceptable for vaginal surgery. So as  
16                   long as they all are within that sort of  
17                   standard, then it's an appropriate  
18                   vaginal application.

19                   Q.     You believe that as long as  
20     a mesh has pore sizes of at least 75  
21     microns that's acceptable?

22                   **A.**       Yes. But most of them are  
23   considerably larger. The weave is -- the  
24   weave is considerably larger.

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1                   **Q.**        Have you ever studied the  
2        question of what happens to the pores of  
3        the PROLIFT® once tension is placed on  
4        them and they're put into the body?

5                   **A.**        Studied is -- I wouldn't  
6        use -- I am not sure what you mean by  
7        "studied," but I've certainly done a lot  
8        of prolapse -- PROLIFT® surgeries and  
9        seen the way the mesh is integrated.

10                  So I don't know what -- I'm  
11        not sure what the question is.

12                  **Q.**        Do you know whether or not  
13        the pores in the PROLIFT® collapse down  
14        when tension is placed on the PROLIFT® in  
15        actual use?

16                  **A.**        In the patient's body?

17                  **Q.**        Yes.

18                  **A.**        I don't have that  
19        experience. It gets integrated and  
20        incorporated and there's no -- the  
21        collapse, it doesn't -- I don't know what  
22        you mean by "collapse." It gets  
23        incorporated.

24                  **Q.**        When tension is placed on

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1     would -- for me what the -- the meaning  
2     of that is. But is that what you mean,  
3     what it means to me?

4                   **Q.**     No. I want to know what --  
5     if you understand, from a scientific  
6     basis, based on the information that's  
7     out there in the medical and scientific  
8     community, among people who study that  
9     question, if you know the answer to it.

10                  MR. BALL: Object to the  
11                  form.

12                  THE WITNESS: I understand  
13                  the importance of pore size in  
14                  mesh. That I understand.

15     BY MR. SLATER:

16                  **Q.**     I asked about 1 milliliter.  
17     Do you know the importance of that for  
18     clinical implications?

19                  **A.**     I do.

20                  **Q.**     And what is your  
21     understanding?

22                  **A.**     My understanding is that  
23     mesh with a certain pore size will allow  
24     macrophages and cells to get through the

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1 mesh so that bacteria can be eliminated.

2 Q. In terms of how scar tissue  
3 forms, do you have any knowledge about  
4 the significance or lack of significance  
5 of a 1 millimeter pore size?

6 MR. BALL: Object to the  
7 form.

8 THE WITNESS: In terms --  
9 can you define what you mean by  
10 "scar tissue"?

11 BY MR. SLATER:

12 Q. Yes. Fibrotic tissue that  
13 forms as part of the inflammatory  
14 response to the foreign body.

15 Do you have any knowledge of  
16 whether or not a 1 millimeter pore size  
17 has any significance for how that scar  
18 tissue will form on the mesh?

19 A. I don't use --

20 MR. BALL: Object to the  
21 form.

22 THE WITNESS: Yeah, "scar  
23 tissue" is not some -- a  
24 terminology -- a term that I would

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1 MR. SLATER: Objection.

2 Your questions are leading.

3 MR. BALL: Okay. All right.

4 I'll start over. Let me finish  
5 them, though. You got me all --  
6 you got me all confused because I  
7 hadn't finished.

8 MR. SLATER: I thought you  
9 were done. You asked for a list.  
10 Well, it's multi-part too. Ask  
11 Bettina, she knows. Compound  
12 queen.

13 BY MR. BALL:

14 Q. Have you -- have you  
15 reviewed the patient brochure, the IFU  
16 and the professional education materials  
17 in existence before Ms. Budke's surgery?

18 MR. SLATER: Objection.

19 Foundation. Leading.

20 MR. BALL: Go ahead and  
21 answer.

22 THE WITNESS: I have  
23 reviewed those materials.

24 BY MR. BALL:

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1                   Q.     Do you believe that they  
2     were adequate for a -- for the purposes  
3     of a surgeon like you, in terms of  
4     determining the risks and benefits of  
5     PROLIFT® and counseling your patients?

6                   MR. SLATER: Objection.

7                   You can answer.

8                   THE WITNESS: Yes, they were  
9     adequate.

10    BY MR. BALL:

11                   Q.     Okay. Then, last question,  
12    in your experience, does the mesh used in  
13    PROLIFT® potentiate infection less than  
14    other foreign materials?

15                   MR. SLATER: Objection.

16                   MR. BALL: Go ahead.

17                   THE WITNESS: Yes, it does.

18                   The PROLIFT® mesh is a Type 1  
19    polypropylene mesh, which is --  
20    has a very low infection rate, as  
21    evidenced by the literature.

22                   We've used prolene sutures for  
23    years. And it potentiates  
24    infection much less than most

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1 CERTIFICATE

2

3

4 I HEREBY CERTIFY that the  
5 witness was duly sworn by me and that the  
6 deposition is a true record of the  
7 testimony given by the witness.

8

9

10

Amanda Maslynsky-Miller

11

Certified Realtime Reporter

Dated: October 15, 2014

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18 of this transcript does not apply to any  
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21 supervision of the certifying reporter.)

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